UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/523,479	09/16/2005	Magdalene M. Moran	110313.138US2	6126

23483 7590 05/05/2008

WILMERHALE/BOSTON
60 STATE STREET
BOSTON, MA 02109

EXAMINER
MONTANARI, DAVID A

ART UNIT	PAPER NUMBER
1632	

NOTIFICATION DATE	DELIVERY MODE
05/05/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

michael.mathewson@wilmerhale.com
teresa.carvalho@wilmerhale.com
sharon.matthews@wilmerhale.com

Office Action Summary	Application No.	Applicant(s)	
	10/523,479	MORAN ET AL.	
	Examiner	Art Unit	
	DAVID MONTANARI	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 February 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-74* is/are pending in the application.

4a) Of the above claim(s) *1-4 and 6-74* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *04 February 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/14/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group V (claim 5) in the reply filed on 2/7/2008 is acknowledged.

Claims 1-4 and 6-74 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 2/7/2008.

1. Claim 5 is examined in the instant application.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 5 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated nucleic acid encoding a polypeptide having at least 95% amino acid sequence identity with a polypeptide selected from the group consisting of: (a) a human or mouse CatSper3 protein; (b) at least a transmembrane domain of a human or mouse CatSper3 protein; (c) at least an extracellular loop of a human or mouse CatSper3 protein; and (d) at least a pore region of a human or mouse CatSper3 protein, does not reasonably provide enablement for an isolated nucleic acid encoding a polypeptide having at least 80% amino acid sequence identity with a polypeptide selected from the group consisting of: (a) any CatSper3 protein; (b) at least a

transmembrane domain of any CatSper3 protein; (c) at least an extracellular loop of any CatSper3 protein; and (d) at least a pore region of any CatSper3 protein. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

While determining whether a specification is enabling, one considers whether the claimed invention provides sufficient guidance to make and use the claimed invention, if not, whether an artisan would have required undue experimentation to make and use the claimed invention and whether working examples have been provided. When determining whether a specification meets the enablement requirements, some of the factors that need to be analyzed are: the breadth of the claims, the nature of the invention, the state of the prior art, the level of one of ordinary skill, the level of predictability in the art, the amount of direction provided by the inventor, the existence of working examples, and whether the quantity of any necessary experimentation to make or use the invention based on the content of the disclosure is "undue" (In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)). Furthermore, USPTO does not have laboratory facilities to test if an invention will function as claimed when working examples are not disclosed in the specification, therefore, enablement issues are raised and discussed based on the state of knowledge pertinent to an art at the time of the invention, therefore skepticism raised in the enablement rejections are those raised in the art by artisans of expertise.

The breadth of the claim encompasses an isolated nucleic acid encoding non-functional transmembrane domains, extracellular loops and pore regions of the CatSper3 protein.

Whereas the nature of the invention is a an isolated nucleic acid sequence that encodes the CatSper3 protein and its functional regions, the breadth of the claim encompasses an

inoperable embodiment that at least 80% amino acid sequence identity of any isolated nucleic acid with the CatSper3 protein will yield functional regions or a CatSper3 protein. At particular issue is the 80% sequence identity that is present in the instant claim. In view of the teachings in the specification and the art discussed below the scope of enablement above is drawn to an isolated nucleic acid sequence that is 95% sequence identical to an amino acid sequence with a CatSper3 protein or one if its functional domains. The specification teaches on pages 16 and 17, starting with the last parag., specific nucleotide regions that will comprise the pore region and extracellular domains. Further the specification continues to teach the six transmembrane domains in Fig. 1 and 2 for both human and mouse CatSper3. The specification continues that each of the regions discussed above in the nucleotide sequences are an approximation and not definite. This is problematic for the skilled artisan because the 80% sequence identity in the instant claim could result in a non-functional region that will not enable the claimed invention. The instant specificatation has failed to teach what is the minimum or essential nucleotide sequence that would result in, for example, a transmembrane domain of a CatSper3 protein. The specification has identified approximate regions spanning the CatSper3 sequence that will most likely yield a transmembrane domain, but for the skilled artisan to take any 80% of the approximate identified regions for any given functional sequence would result in significant experimentation. For example Jin et al. teach the comparison of the CatSper3 sequence (pore and transmembrane domain) from mouse, rat, dog, chimpanzee and human (see pg. 1236, Fig. 1. Jin et al., Biol. Reproduction, 2005, Vol. 73, pgs. 1235-1242). Jin continues to teach that the sequence identity of CatSper3 can vary significantly across species from as low as 66.1% (mouse vs. human) to 99.2% (chimpanzee vs. human) (Fig. 1B). Given this variability, the breadth of the

claim encompassing CatSper3 from any species of animal, that all identified nucleotide regions are approximations (also taught by Jin et al.) and that the 80% sequence identity could come from any sequence of nucleotide identified in the art or the specification, the skilled artisan would require an undue amount of experimentation without a predictable degree of success to produce an isolated nucleotide sequence that would yield a functional domain as instantly claimed. As discussed above the claim has been scoped to a 95% sequence identity, which will yield a far more conservative sequence that the skilled artisan would accept as most likely yielding a functional CatSper3 protein or functional domain. The specification also teaches that CatSper3 is exclusively expressed in only testis (pg. 9 line 18), and thus at a minimum the claimed isolated nucleotide sequence could only be derived from animals that have testis.

Thus base upon the teachings in the art and specification above the claimed invention is not enabled for its entire breadth and limiting the scope of the invention to an isolated nucleic acid encoding a polypeptide having at least 95% amino acid sequence identity with a polypeptide selected from the group consisting of: (a) a human or mouse CatSper3 protein; (b) at least a transmembrane domain of a human or mouse CatSper3 protein; (c) at least an extracellular loop of a human or mouse CatSper3 protein; and (d) at least a pore region of a human or mouse CatSper3 protein is proper.

Claim 5 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

When the claim is analyzed in light of the specification, the instant invention encompasses any isolated nucleic acid sequence that encodes a polypeptide having an amino acid sequence identity with a polypeptide encoding a CatSper3 protein. However, the specification teaches only the nucleotide sequences disclosed in SEQ ID NO:s 1 and 3. In analyzing whether the written description requirement is met for genus claims, it is first determined whether a representative number of species have been described by their complete structure. In the instant case, only SEQ ID NO: 1 (human) and SEQ ID NO: 2 (mouse) are the only species whose complete structure is disclosed. The specification does not provide any disclosure as to what the complete structure would be of any isolated nucleotide sequence that would encode a CatSper3 protein. The specification teaches structural analysis of only SEQ ID NO's 1 and 3. Next, then, it is determined whether a representative number of species have been sufficiently described by other relevant identifying characteristics (i.e. other than nucleotide sequence), specific features and functional attributes that would distinguish different members of the claimed genus. In the instant case, the only characteristic described, is the nucleotide sequence and functional domains present in SEQ ID NOs 1 and 3. The specification does not teach any other identifying characteristic or any other related sequences that would guide the artisan to contemplate other nucleotide sequences that would encode for a CatSper3 protein.

Applicants' attention is directed to the decision in In re Shokal, 113, USPQ 283 (CCPA 1957) wherein is stated:

It appears to be well settled that a single species can rarely, if ever, afford sufficient support for a generic claim, In re Soll, 25 C.C.P.A. (Patents) 1309, 97, F.2d 623, 38 USPQ 189; In re Wahlforss et al., 28 C.C.P.A. (Patents) 867, 117 F.2d 270, 48 USPQ 397. The decisions do not however fix any definite number of species which will establish completion of a generic invention and it seems evident therefrom that such a number will vary, depending on the circumstances of particular cases. Thus, in the case of small genus such as halogens, consisting of four species, a reduction in practice of three, or perhaps even two,

might server to complete the generic invention, while in the case of a genus comprising hundreds of species, a considerably larger number of reductions to practice would probably be necessary.

In conclusion, this limited information is not deemed sufficient to reasonably convey to one skilled in the art that applicant is in possession of any nucleotide sequence that encodes a CatSper3 protein other than those sequences disclosed in SEQ ID NOs 1 and 3.

No claims are allowed.

Claim 5 is free of the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID MONTANARI whose telephone number is (571)272-3108. The examiner can normally be reached on M-Tr 8-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 1-571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

David A. Montanari, Ph.D.

/Anne-Marie Falk/
Anne-Marie Falk, Ph.D.
Primary Examiner, Art Unit 1632